Docket No.: PF-0261-2 DIV

REMARKS

The Examiner states that "[b]ecause applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse" (Office Action, April 11, 2003; page 2; ¶ 1). Applicants traverse the treatment of the election as an election without traverse.

In the Response to Restriction Requirement mailed March 5, 2003, Applicants traversed the requirement to elect either the polypeptides of the invention, the antibodies of the invention, the polynucleotides of the invention, or various groups of method claims. Applicants pointed out that claims directed to using the claimed antibodies "could and should be examined together" with the elected antibody claims, and distinctly and specifically pointed out the errors in the restriction requirement. For example, Applicants cited the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)" as evidence of the impropriety of the Patent Office's refusal to examine process claims together with the product claims from which they depend.

Furthermore, Patent Office policy is that "[i]f the search and examination of an entire application can be made without <u>serious burden</u>, the examiner <u>must</u> examine it on the merits, even though it includes claims to independent or distinct inventions." M.P.E.P. § 803 (emphasis added). Therefore, Applicants distinctly and specifically pointed out that the restriction requirement was erroneous by stating that "claim 1, drawn to polypeptides of the invention, could be examined along with the antibody claims without undue burden on the Examiner. A search for prior art to determine the novelty of the antibodies would substantially overlap with a search of the prior art to determine the novelty of the polypeptides specifically bound by the antibodies" (Response to Restriction Requirement, March 5, 2003; page 7).

For at least the above reasons, it is believed that Applicants' election of March 5, 2003, should be treated as an election <u>with traverse</u>.

The instant Restriction Requirement asserts that the claims are directed to patentably distinct species comprising an antibody that binds to a fragment of SEQ ID NO:1 selected from (a) residues A90-L102 of SEQ ID NO:1, (b) residues D213-Y225 of SEQ ID NO:1, (c) residues

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D254-V266 of SEQ ID NO:1, and (d) residues D290-I302 of SEQ ID NO:1. In response to this Restriction Requirement, <u>Applicants hereby elect species (c)</u>, comprising antibodies which specifically bind to a fragment of a polypeptide of SEQ ID NO:1, wherein the fragment comprises residues D254-V266 of SEQ ID NO:1, with traverse.

The traversal is based in part on the Patent Office guidelines for restriction as set out in the M.P.E.P. at § 803:

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

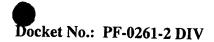
- (A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 § 806.05(i)); and
- (B) There must be a serious burden on the examiner if restriction is required (see MPEP \S 803.02, \S 806.04(a) \S 806.04(i), \S 808.01(a), and \S 808.02).

At the very least, the restriction is improper because it does not meet the second of these criteria. There is no serious burden to examine all four of the restricted species together because a search and examination of each of these four species would significantly overlap with a search and examination of claims directed to antibodies which specifically bind to a polypeptide comprising SEQ ID NO:1, or to antibodies which specifically bind to a calcium-binding fragment of SEQ ID NO:1. For example, each of the fragments of SEQ ID NO:1 comprising residues A90-L102, residues D213-Y225, residues D254-V266, and residues D290-I302 is disclosed in the specification to be a calcium-binding EF-hand motif (e.g., at page 10, lines 10-11). Therefore, each of the restricted species are **examples** of antibodies which specifically bind to calcium-binding fragments of SEQ ID NO:1.

Furthermore, the restriction is improper because the Office Action has made unsupported assertions that the four restricted species are patentably distinct. The M.P.E.P. requires that "Examiners must provide reasons and/or examples to support conclusions, but need not cite documents to support the restriction requirement in most cases." M.P.E.P. § 803. The Office Action has not provided any reasons or examples to show that the four restricted species are patentably distinct. Therefore, the restriction between these species is improper.

For at least the above reasons, Applicants request withdrawal of the restriction between species.

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Applicants reserve the right to prosecute non-elected subject matter in subsequent divisional applications.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned at (650) 621-8581.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108.

Respectfully submitted,
INCYTE CORPORATION

Date: May 5, 2003.

Terence P. Lo, Ph.D.

Limited Recognition (37 C.F.R. § 10.9(b)) attached

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LIMITED RECOGNITION UNDER 37 CFR § 10.9(b)

Terence P. Lo is hereby given limited recognition under 37 CFR § 10.9(b) as an employee of Incyte Genomics Inc. to prepare and prosecute patent applications wherein Incyte Genomics Inc. is the assignee of all right, title and interest in the invention claimed in the application. This limited recognition shall expire on the date appearing below, or when whichever of the following events first occurs prior to the date appearing below: (i) Terence P. Lo ceases to lawfully reside in the United States, (ii) Terence P. Lo's employment with Incyte Genomics Inc. ceases or is terminated, or (iii) Terence P. Lo ceases to remain or reside in the United States on an H-1 visa.

This document constitutes proof of such recognition. The original of this document is on file in the Office of Enrollment and Discipline of the U.S. Patent and Trademark Office.

Expires: November 25, 2003

Harry I. Moatz

Director of Enrollment and Discipline